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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/738,477	12/17/2003	Donald K. Jones	CRD5046	8210

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EXAMINER	
OSINSKI, BRADLEY JAMES	
ART UNIT	**PAPER NUMBER**
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10/15/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/738,477	JONES ET AL.	
	Examiner	Art Unit	
	Bradley J. Osinski	4111	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *17 December 2003*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) *1-16* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *17 and 18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☒ The drawing(s) filed on *17 December 2003* is/are: a)☒ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date *See Continuation Sheet*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Attachment(s) 3). Information Disclosure Statement(s) (PTO/SB/08), Paper No(s)/Mail Date :6 August 2004, 4 August 2005, 17 October 2005, 30 May 2006, and 30 April 2007 .

DETAILED ACTION

Election/Restrictions

1. Restriction to one of the following inventions is required under 35 U.S.C. 121:

   I. Claims 1-16, drawn to a medical device, classified in class 604, subclass 533

   II. Claims 17-18, drawn to a method of treatment, classified in class 604, subclass 508

The inventions are distinct, each from the other because of the following reasons:

2. Inventions I and II are related as product and process of use. The inventions can be shown to be distinct if either or both of the following can be shown: (1) the process for using the product as claimed can be practiced with another materially different product or (2) the product as claimed can be used in a materially different process of using that product. See MPEP § 806.05(h). In the instant case the medical device of invention I can be used in a materially different process in which the external agent is not applied via the catheter, but can instead be delivered in a different process such as orally or via local injection. The invention of I can also be used in a materially different process in which the device itself is delivered by means other than a catheter, such as a coil along a wire. Reference is made to Wallace et al (US 2002/0143348) which is drawn to an embolic device with an outer soluble layer that is dissolved after the device has been delivered, similar to the current application. "...the solvating liquid agent can be delivered separately from the implantable device, for example, using a different delivery system after deployment of the device." (Paragraph 41)

3. Because these inventions are independent or distinct for the reasons given above and there would be a serious burden on the examiner if restriction is not required because the inventions have acquired a separate status in the art in view of their different classification, restriction for examination purposes as indicated is proper.

4. During a telephone conversation with Michael Montgomery on 11 September 2007 a provisional election was made with traverse to prosecute the invention of II, claims 17-18. Affirmation of this election must be made by applicant in replying to this Office action. Claims 1-16 are withdrawn from further consideration by the examiner, 37 CFR 1.142(b), as being drawn to a non-elected invention.

5. Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Claim Rejections - 35 USC § 103

6. The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

7. Claims 17-18 are rejected under 35 U.S.C. 103(a) as being unpatentable over Wallace et al (US 2002/0143348) in view of Pinchuk et al (2002/0107330). Wallace et al teaches a medical device composed of a support member 2 which is covered in a

polymer that is partly solvated by a liquid agent, after which the surface of the support member 2 is exposed to bodily fluids. "In certain embodiments, the material (e.g. polymer) to be solvated is coated onto the surface of the device(s)..." (Paragraph 43) and "...the liquid agent is capable of solvating polymeric material of the device." (Paragraph 23). Delivery is done via a catheter, "...a large catheter is introduced through an entry site in the vasculature" (Paragraph 46). The tip of the catheter is advanced to the selected site, "Once the distal end of the catheter is positioned at the site, often by locating its distal end through the use of a radiopaque marker material and fluoroscopy, the catheter is cleared." (Paragraph 46). The device is then delivered through the catheter, "The device is advanced past the distal end of the catheter and positioned or extruded precisely at the desired treatment site. " (Paragraph 46), after which the liquid agent is delivered, "The liquid agent is preferably infused after extrusion..." (Paragraph 46)

Wallace et al does not, however specifically teach a bioactive agent disposed between the support member and the barrier nor does he teach the polymer is specifically a barrier. Pinchuk et al, which is partly drawn to aneurysm fillers, "Preferred medical devices for use in conjunction with the present invention include... composites for aneurysm fillers" (Paragraph 180), does teach a barrier layer of polymers, "In some instances, it may be desirable to temporarily enclose the therapeutic-agent-loaded copolymer to prevent release before the medical device reaches its ultimate placement site." (Paragraph 183) and "It also may be useful to coat the copolymer of the present invention (which may or may not contain a therapeutic agent) with an additional polymer

layer (which may or may not contain a therapeutic agent). This layer may serve, for example, as a boundary layer to retard diffusion of the therapeutic agent and prevent a burst phenomenon whereby much of the agent is released immediately upon exposure of the device or device portion to the implant site." (Paragraph 204) The polymers taught by Wallace et al such as polyvinylpyrrolidone, polyesters, polyethylene, etc (paragraph 30) are also many the polymers taught by Pinchuk et al. (Paragraph 205) Wallace et al does teach, "The devices, assemblies, and methods described herein may also include one or more bioactive materials... for example a thrombotic agent... " (Paragraph 39, emphasis added) Therefore it would have been obvious to one of ordinary skill in the art to form a medical device of Wallace et al such that a thrombotic agent is disposed between a polymer coating and support member because: a) as noted above, Wallace et al teaches the device may include a thrombotic agent, and b) Pinchuk suggests coating with a polymer identical to the polymers of Wallace et al to "...prevent release before the medical device reaches its ultimate placement site." (Paragraph 183)

Double Patenting

8. The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. A nonstatutory obviousness-type double patenting rejection is appropriate where the conflicting claims are not identical, but at least one examined application claim is not patentably distinct from the reference claim(s) because the examined application claim is either anticipated by, or would have been obvious over, the reference claim(s). See, e.g., *In re Berg*, 140 F.3d 1428, 46 USPQ2d 1226 (Fed. Cir. 1998); *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422

F.2d 438, 164 USPQ 619 (CCPA 1970); and *In re Thorington*, 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) or 1.321(d) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent either is shown to be commonly owned with this application, or claims an invention made as a result of activities undertaken within the scope of a joint research agreement.

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

9. Claims 17 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26 and 27 of copending Application No. 10/868152. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods and claim providing a medical device (in the copending application a vascular device is claimed) that is comprised of a support member, a bioactive agent disposed on the support member and a barrier that normally prevents a reaction between the coating and bodily fluid that exposes the bioactive agent when an external agent is applied to the barrier. Also claimed is inserting a delivery catheter into a blood vessel, advancing the distal tip of the delivery catheter to the site within a blood vessel, delivering the medical device to the selected site, and applying he external agent through the catheter into the blood vessel to activate the barrier and cause a reaction between the bioactive agent and bodily tissue. (In the copending applications case, the reaction is the expansion of the bioactive coating.)

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

10. Claims 17 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 26 and 27 of copending Application No. 10738473. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods and claim providing a medical device (in the copending application a vascular device is claimed) that is comprised of a support member, a bioactive agent disposed on the support member and a barrier that normally prevents a reaction between the coating and bodily fluid that exposes the bioactive agent when an external agent is applied to the barrier. Also claimed is inserting a delivery catheter into a blood vessel, advancing the distal tip of the delivery catheter to the site within a blood vessel, delivering the medical device to the selected site, and applying he external agent through the catheter into the blood vessel to activate the barrier and cause a reaction between the bioactive agent and bodily tissue.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

11. Claims 17 and 18 are provisionally rejected on the ground of nonstatutory obviousness-type double patenting as being unpatentable over claims 49 and 50 of copending Application No. 10874864. Although the conflicting claims are not identical, they are not patentably distinct from each other because both applications are drawn to methods and claim providing a medical device (in the copending application a vascular

device is claimed) that is comprised of a support member, a bioactive agent disposed on the support member and a barrier that normally prevents a reaction between the coating and bodily fluid that exposes the bioactive agent when an external agent is applied to the barrier. Also claimed is inserting a delivery catheter into a blood vessel, advancing the distal tip of the delivery catheter to the site within a blood vessel, delivering the medical device to the selected site, and applying he external agent through the catheter into the blood vessel to activate the barrier and cause a reaction between the bioactive agent and bodily tissue.

This is a provisional obviousness-type double patenting rejection because the conflicting claims have not in fact been patented.

Conclusion

12. The prior art made of record and not relied upon is considered pertinent to applicant's disclosure.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Bradley J. Osinski whose telephone number is (571)270-3640. The examiner can normally be reached on Monday-Thursday 9AM-5PM EST.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Sam Yao can be reached on (571)272-1224. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

bjo

SAMCHUAN C. YAO
SUPERVISORY PATENT EXAMINER